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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,716	09/21/2001	Grigoriy S. Tchaga	CLON-060	4277

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,716

Applicant(s)

TCHAGA, GRIGORIY S.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the same buffer composition" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al., 6,207,369, in view of Kartel et al., "Evaluation of Pectin Binding of Heavy Metal Ions in Aqueous Solutions", Chemosphere, Vol. 38, No. 11, pp. 2591-2596, 1999.

Wohlstadter et al. teach the invention substantially as claimed. More specifically, Wohlstadter et al. disclose a method of determining whether a sample includes an analyte of interest (col. 8, line 29), said method comprising:

contacting said sample with a planar array of a plurality of distinct binding agents (i.e., array of binding domains 48, and see col. 38, lines 40-41, disclosing antibodies) displayed on a surface of a solid support (on planar electrode (50), (see figure 3, and col. 42, lines 28-53 and also col. 59, lines 64-66) in the presence of a metal ion chelator (i.e., M1 which is an antibody and can complex with a metal, col. 38, lines 40-49)

wherein each of said binding agents at least comprises a specific epitope binding domain of an antibody (col. 24, lines 24-27, and col. 38, lines 40-41);

detecting the presence of any resultant binding complexes on said surface to obtain analyte binding data (col. 27, line 26);

and employing said analyte binding data to determine whether said sample includes said at least one analyte of interest (col. 27, line 26)

However, Wohlstadter et al. do not teach that the metal chelating element (M1 in col. 38, lines 49) is a polysaccharide, such as apple pectin (as claimed in claims 1, 3-5 and 14-16). However, Kartel et al. teach this element.

Kartel et al. teach that polysaccharides such as apple pectin is a metal chelator that has a high selectivity for certain metals (see page 2591-2592 and page 2595.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize apple pectin as the metal ion chelator generally disclosed by

Wohlstadter et al. because Kartel et al. teach that apple pectin is a metal chelator that has a high selectivity for certain metals.

As to the following claims, Wohlstadter teaches the limitations as follows.

As to claim 6, said method further comprises extracting said at least one analyte from a cellular source (col. 18, lines 11-13) and labeling said extracted at least one analyte (i.e, labeling with labeled secondary antibodies, col. 38, line 45), wherein said extracting and labeling steps employ the same buffer composition (col. 80, line 66) Since Applicant has not specifically defined how the extracting step is carried out, Examiner interprets the step of adding buffer (in col. 80, line 66) as part of the extracting step.

As to claim 7, said buffer composition is free of components that include primary amine moieties (see for example col. 95, lines 27-28.)

As to claim 8, said buffer composition has a pH ranging from about 7 to about 12 (col. 91, line 33.)

As to claim 9, said buffer composition is capable of extracting at least about 95% of the proteins of an initial cellular source (col. 95, lines 27-28.)

As to claim 10, said at least one analyte is a protein (col. 24, line 26.)

As to claim 11, said method comprises determining the presence of at least two distinct analytes (col. 8, line 6 and 23) in said sample.

As to claim 12, said method comprises a plurality of washings steps between said contacting and detecting steps (col. 91, lines 30-35.)

As to claim 13, Wohlstadter teaches detecting at least two different protein analytes (i.e., array of binding domains 48), and extracting at least one analyte from a cellular source (col. 18, lines 11-17), and labeling the extracted analyte (col. 38, lines 44-46) in the same buffer composition as the extracting step and employing a plurality of washing steps between the contacting and detecting steps (col. 14, lines 34-35.) (Examiner notes that the claim does not specify that the different proteins are different types of proteins. The type of buffer composition is also not specified and thus the buffer is considered to be the solution of analyte. The method of the washing steps is also not specified and thus the washing disclosed in column 14, lines 34-35 is considered the washing steps.)

As to claim 17, the method is considered a method of determining a protein expression profile for the sample, since it is a method of determining the presence of a protein in a biological fluid sample such as whole blood (col. 18, lines 11-13.)

As to claim 18, said method further comprises a sample fractionating step prior to said contacting step (i.e., use of filter for removing cells from blood, col. 44, lines 21-22.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al., 6,207,369, in view of Kartel et al., "Evaluation of Pectin Binding of Heavy Metal Ions in Aqueous Solutions", Chemosphere, Vol. 38, No. 11, pp. 2591-2596, 1999, as applied to claims 1 and 18, and further in view of Moyer et al., 3,791,933.

Wohlstadter discloses the invention substantially as claimed (see above). More specifically Wohlstadter teaches that a filter may be included for removing cells from blood prior to the assaying steps (col. 44, lines 21-24.) This is considered to be the fractionating step in Applicant's claims. However Wohlstadter does not teach that the fractionating step comprises contacting a sample with at least one affinity column.

Moyer discloses that a stacked array of filter discs confined in a column which is adapted for placement of a fluid test media may be used to filter out blood cells from a test sample in an assay for the detection of an analyte (col. 3, lines 51-52, and col. 9, lines 34-56.)

It would have been obvious to one of ordinary skill in the art to substitute the stacked filter discs taught by Moyer for the membrane in Wohlstadter as a functional equivalent since both are used to filter out blood cells from a test sample in an assay for the detection of an analyte.

Response to Arguments

Upon reconsideration, the claims are anticipated by the prior art as described above.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Johnson et al., 5,057,302, discloses bifunctional chelating agents comprising an antibody and any metal ion chelator of choice depending on the metal ion to be bound.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



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11/28/05